510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

JUN 12 2009

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Senior Regulatory Affairs Associate Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@its.jnj.com
DATE PREPARED:	May 13, 2009
PROPRIETARY NAME:	DePuy Pinnacle® 100 with Griptionᵀᴹ Acetabular Cups
COMMON NAME:	Acetabular Cup with Porous Coating
CLASSIFICATION:	Class III per 21 CFR 888.3330: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis Class II per 21 CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
DEVICE PRODUCT CODE:	KWA, JDI, LZO and LPH
SUBSTANTIALLY EQUIVALENT DEVICES:	Pinnacle with Griptionn Acetabular Cups, **K071784** (July 25, 2007) Pinnacle Acetabular System (Porocoat), **K001534** (June 12, 2000)

DEVICE DESCRIPTION:

The Pinnacle Acetabular System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner manufactured from ultra high molecular weight polyetheylene (UHMWPE) or high-carbon cobalt chrome (CrCoMo), both of which lock into the outer shell. The liner component articulates with a femoral head of an appropriate diameter. The subject acetabular cup is coated with a proprietary titanium porous coating, Gription.

INDICATIONS AND INTENDED USE:

Indications:

The Pinnacle 100 with Gription Acetabular Cup is indicated for use as part of the acetabular portion of a total hip replacement.

Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Porous-coated Pinnacle Acetabular Cups are indicated for cementless applications.

Intended Use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Pinnacle 100 with Gription Acetabular Cup is substantially equivalent in geometry to the Pinnacle 100 Acetabular Cups (with Porocoat) cleared in K001534, and substantially equivalent in porous coating to the Pinnacle Cups with Gription cleared in K071784 based on similarities in intended use, indications for use, material, design, sterilization, packaging and method of manufacturing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

DePuy Orthopaedics, Incorporated
c/o Ms. Rhonda Myer
Senior Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K090998
Trade/Device Name: DePuy Pinnacle 100 with Gription Acetabular Cups
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip Joint Metal/Metal Semi-Constrained, With an Uncemented Acetabular Component, Prosthesis
Regulatory Class: Class III
Product Code: KWA, JDI, LZO, LPH
Dated: May 14, 2009
Received: May 15, 2009

Dear Ms. Myer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090998

Indications for Use Statement

510 (k) Number (if known): K090998

Device Name: **DePuy Pinnacle® 100 with Gription™ Acetabular Cup**

Indications for Use:

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090998